NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC) GUIDELINE SYNTHESIS

MANAGEMENT OF OBSTRUCTIVE SLEEP APNEA (OSA)

GUIDELINES BEING COMPARED

1. **American Academy of Sleep Medicine (AASM)**
   a. Practice parameters for the medical therapy of obstructive sleep apnea. Sleep 2006a Aug 1;29(8):1031-5. [65 references]
   b. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances: an update for 2005. Sleep 2006b Feb 1;29(2):240-3. [8 references]
   c. Practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders. Sleep 2006c Mar 1;29(3):375-80. [94 references]
   d. Practice parameters for the use of autotitrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea syndrome: an update for 2007. Sleep 2008 Jan 1;31(1):141-7. [40 references]
2. **Institute for Clinical Systems Improvement (ICSI)**. Diagnosis and treatment of obstructive sleep apnea in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Jun. 55 p. [119 references]

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AREAS OF AGREEMENT AND DIFFERENCE

A direct comparison of American Academy of Sleep Medicine (AASM) and Institute for Clinical Systems Improvement (ICSI) recommendations for the management of obstructive sleep apnea (OSA) is provided below.

Areas of Agreement

CPAP

According to ICSI, positive pressure is the most efficacious (next to tracheostomy) for treating OSA, and CPAP is currently the most commonly used PAP device. AASM 2006c, which focuses solely on PAP, concurs, noting that CPAP is a standard treatment for patients with OSA, and a standard of care for treating moderate to severe OSA. The groups agree that CPAP is recommended for mild, as well as moderate to severe OSA. AASM also recommends CPAP for improving quality of life and self-reported sleepiness in patients with OSA. For hypertensive patients with OSA, AASM also recommends CPAP as an adjunctive therapy to lower blood pressure.

Both groups stress the importance of patient compliance, proper mask/interface fit, and frequent follow-up. AASM 2006c and ICSI agree that that the addition of heated humidification and patient education programs are indicated to improve PAP utilization.

BPAP

BPAP is addressed by AASM 2006c and ICSI. According to ICSI, BPAP can have advantages for selected patients who do not tolerate CPAP or APAP. AASM similarly notes that BPAP may be appropriate in cases where high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure or coexisting central hypoventilation is present. The groups agree that BPAP may also benefit those with concurrent or more severe lung diseases or hypoventilation syndromes associated with daytime hypercapnia. Both groups note, however, that BPAP devices have not been demonstrated to be superior to CPAP and should not be used as initial treatment for OSA.

APAP

AASM 2008 and ICSI provide recommendations for APAP. According to ICSI, APAP may be used as an alternative therapy for patients who are intolerant of pressures in conventional CPAP therapy, and may be used for an unattended in-home CPAP titration after a positive sleep study or when follow-up indicates a need for CPAP pressure change. AASM similarly notes that APAP may be used during attended titration with polysomnography to identify a single pressure for use with standard CPAP for treatment of moderate to severe OSA. AASM also states, for patients with moderate to severe OSA without significant comorbidities (CHF, COPD, central sleep apnea syndromes, or hypoventilation syndromes), certain APAP devices may be used in the self-adjusting mode for unattended treatment, or in an unattended way to determine a fixed CPAP treatment pressure. AASM notes, however, that patients with CHF, significant lung disease such as COPD, patients expected to have nocturnal arterial oxyhemoglobin desaturation due to conditions other than OSA, patients who do not snore, and patients who have central sleep apnea syndromes are not currently candidates for APAP titration or treatment.

Weight Reduction

AASM 2006a and ICSI agree that there is a strong association between obesity and OSA and that weight reduction may improve the condition. AASM recommends combining dietary weight loss with a proven treatment (such as PAP, oral devices, or surgery) in obese patients with OSA. According to ICSI, weight loss should be encouraged even in those OSA patients who are only moderately overweight, and a nurse-managed program of calorie restriction and behavior management is safe and cost-effective as a primary treatment for OSA. The role of bariatric surgery in OSA patients is discussed below.

Position Therapy

AASM 2006a and ICSI agree that sleeping with the body in a non-supine position can be effective for reducing apnea/hypopnea. According to ICSI, both the frequency of apneic events and their severity are worse in the supine than the lateral position. AASM indicates positioning is most likely to be effective in patients who are younger, less obese and have less severe OSA, and states that positioning should be used only as a supplement to primary therapies for OSA. AASM also recommends that when position therapy is used, an appropriate test should be performed to document the correction of OSA.

Oral Appliances

AASM 2006b and ICSI agree that patients with non-severe OSA are the most appropriate candidates for OAs. According to AASM, OAs are appropriate for patients with mild to moderate OSA who: are not candidates for CPAP, prefer OAs to CPAP, or fail attempts at CPAP treatment or lifestyle modification. Although OAs can be used to manage severe OSA, AASM states that patients should first try CPAP because of its greater effectiveness; upper airway surgery may also supersede use of OAs for patients with severe OSA. Similarly, ICSI recommends OAs for patients with mild OSA who have first tried and failed at lifestyle modification. Like AASM, ICSI recommends OAs for patients who cannot tolerate PAP.

AASM recommends that qualified dental personnel fit the OA and that a practitioner with training in sleep medicine oversee the dental management of the patient; ICSI does not specifically address this topic, although they do provide resources for locating qualified dental practitioners. AASM recommends follow-up care to allow adjustment of the appliance and assessment of OSA control. They also recommend that patients undergo polysomnography or an attended cardiorespiratory sleep study with the OA in place after final adjustments of fit have been made. In addition, AASM specifies that once a good fit has been attained, patients should have follow-up visits with the dental specialist every 6 months during the first year and annually thereafter. Patients also should have follow-up visits with the referring clinician to monitor OSA control and, if control appears to worsen, clinicians should objectively reevaluate respiration during sleep.

Pharmacologic Therapy

AASM 2006a and ICSI address pharmacological therapy. AASM concludes that SSRIs, protriptyline, methylxanthine derivatives, estrogen therapy, and short-

acting nasal decongestants cannot be recommended. They suggest, however, that topical nasal corticosteroids may be a useful adjunct to primary therapy in patients with comorbid rhinitis.

With regard to modafinil, AASM recommends it for the treatment of residual excessive daytime sleepiness in OSA patients who have sleepiness despite effective PAP treatment and who are lacking any other identifiable cause for their sleepiness. ICSI notes that while modafinil has been approved by the FDA for treatment of excessive sleepiness associated with OSA, they recommend that a thorough evaluation of risks and benefits be done before prescribing this medication.

Surgical Interventions

While surgical interventions are outside the scope of the AASM guidelines, AASM 2006a notes that bariatric surgery may be adjunctive in the treatment of OSA in obese patients, and AASM 2006b states that upper airway surgery may supersede the use of OAs in patients for whom these operations are predicted to be highly effective in treating OSA.

Similar to AASM 2006a, ICSI notes that morbidly obese patients with OSA may benefit from bariatric surgery, although it must be remembered, they add, that long-term recurrence of the syndrome is possible. In addition to bariatric surgery, ICSI also addresses the following surgical procedures available for the treatment of symptomatic anatomical obstructions of the upper airway that contribute to or result in mild clinical OSA: septoplasty, nasal polypectomy, tonsillectomy, turbinoplasty, tracheostomy, uvulopalatopharyngoplasty, pillar procedures, radiofrequency ablation, hyoid suspension, and mandibular advancement.

Areas of Difference

There are no significant areas of difference between the guideline recommendations.

COMPARISON OF RECOMMENDATIONS	
NON-SURGICAL INTERVENTIONS **Abbreviations** **Back to TOC**	
Lifestyle Modifications	
AASM (2006a)	**Weight Reduction** Successful dietary weight loss may improve the AHI in obese OSA patients. **(Guideline)** Dietary weight loss should be combined with a primary treatment

	for OSA. **(Option)** **Positional Therapies** Positional therapy, consisting of a method that keeps the patient in a non-supine position, is an effective secondary therapy or can be a supplement to primary therapies for OSA in patients who have a low AHI in the non-supine versus that in the supine position. **(Guideline)**
AASM (2006b)	No recommendations offered.
AASM (2006c)	No recommendations offered.
AASM (2008)	No recommendations offered.
ICSI (2008)	**Lifestyle Modification** The following lifestyle modifications can play a significant role in the reduction of severity of sleep apnea symptoms: • Weight loss • Reduced alcohol consumption, especially before bedtime • Lateral body position during sleep (versus supine) • Good sleep hygiene • Integrate PAP preparation into a bedtime routine and bedroom environment **Obesity** Weight loss should be encouraged as a specific treatment for patients with OSA, including those who are only moderately overweight. A nurse-managed program combining a very low calorie diet with behavior management on an outpatient basis is safe and cost effective as a primary treatment for OSA *[D]*. See Appendix D, "Sleep Hygiene" in the original guideline document for more information. Refer to the original guideline document for more information on alcohol consumption, obesity, and body position.
Positive Airway Pressure (PAP) Devices	
AASM (2006a)	No recommendations offered.

AASM (2006b)	Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Upper airway surgery (including tonsillectomy and adenoidectomy, craniofacial operations, and tracheostomy) may also supersede use of oral appliances in patients for whom these operations are predicted to be highly effective in treating sleep apnea. **(Guideline)**
AASM (2006c)	Treatment with CPAP must be based on a prior diagnosis of OSA established using an acceptable method **(Standard)**. CPAP is indicated for the treatment of moderate to severe OSA **(Standard)**. CPAP is recommended for the treatment of mild OSA **(Option)**. CPAP is indicated for improving self-reported sleepiness in patients with OSA **(Standard)**. CPAP is recommended for improving quality of life in patients with OSA **(Option)**. CPAP is recommended as an adjunctive therapy to lower blood pressure in hypertensive patients with OSA **(Option)**. Full-night, attended polysomnography performed in the laboratory is the preferred approach for titration to determine optimal positive airway pressure; however, split-night, diagnostic-titration studies are usually adequate **(Guideline)**. CPAP usage should be objectively monitored to help assure utilization **(Standard)**. Close follow-up for PAP usage and problems in patients with OSA by appropriately trained health care providers is indicated to establish effective utilization patterns and remediate problems, if needed. This is especially important during the first few weeks of PAP use **(Standard)**. The addition of heated humidification is indicated to improve CPAP utilization **(Standard)**. The addition of a systematic educational program is indicated to improve PAP utilization **(Standard)**. After initial CPAP setup, long-term follow-up for CPAP-treated patients with OSA by appropriately trained health care providers is indicated yearly and as needed to troubleshoot PAP mask, machine,

	or usage problems **(Option)**. CPAP and BPAP therapy are safe; side effects and adverse events are mainly minor and reversible **(Standard)**. While the literature mainly supports CPAP therapy, BPAP is an optional therapy in some cases where high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure or coexisting central hypoventilation is present **(Guideline)**. BPAP may be useful in treating some forms of restrictive lung disease or hypoventilation syndromes associated with daytime hypercapnia **(Option)**.
AASM (2008)	APAP is not recommended to diagnose OSA. **(Standard)** Patients with CHF, significant lung disease such as COPD, patients expected to have nocturnal arterial oxyhemoglobin desaturation due to conditions other than OSA (e.g., obesity hypoventilation syndrome), patients who do not snore (either naturally or as a result of palate surgery), and patients who have central sleep apnea syndromes are not currently candidates for APAP titration or treatment. **(Standard)** APAP devices are not currently recommended for split-night titration. **(Standard)** Certain APAP devices may be used during attended titration with polysomnography to identify a single pressure for use with standard CPAP for treatment of moderate to severe OSA **(Guideline)** Certain APAP devices may be initiated and used in the self-adjusting mode for unattended treatment of patients with moderate to severe OSA without significant comorbidities (CHF, COPD, central sleep apnea syndromes, or hypoventilation syndromes). **(Option)** Certain APAP devices may be used in an unattended way to determine a fixed CPAP treatment pressure for patients with moderate to severe OSA without significant comorbidities (CHF, COPD, central sleep apnea syndromes, or hypoventilation syndromes). **(Option)**
ICSI (2008)	**Key Points** • Management of mild OSA may include one or more of the following treatment modalities: oral appliances, PAP devices, surgery. • Management of moderate to severe OSA includes the use of

PAP devices. Patients who are intolerant of PAP devices, or those who are not adequately managed with positive airway pressure alone, may be considered for surgery.

PAP Devices

The success of any PAP device therapy depends primarily on patient adherence, which can be enhanced by education, proper mask/interface fit, frequent follow-up by the clinician and DME provider, and finally, A.W.A.K.E. meetings. (See Appendix B, "Management Tips to Improve Adherence with Therapy" in the original guideline document.)

CPAP

Positive pressure is the most efficacious (next to tracheostomy) for treating OSA. CPAP is currently the most commonly used PAP device.

Therapeutic CPAP pressures are generally determined by manual titration during a polysomnogram, resulting in a final fixed pressure that eliminates apneic and hypopneic episodes in all stages of sleep and body positions, diminishes sleep fragmentation, snoring, and oxygen desaturations, thereby improving daytime function. Self-titrating CPAP (AutoPAP) can also be utilized for determining an effective CPAP pressure (see below *[A]*.)

A heated humidifier is strongly suggested in patients with the following circumstances:

- The patient is currently taking drying medications
- Past history of ENT surgeries
- Chronic nasal congestion

In all other patients, it may be cost effective and still improve comfort and adherence by ordering CPAP with heated humidity.

Flexible CPAP is an option that may improve adherence for patients who have difficulty with CPAP.

AutoPAP (AutoPAP, Self-titrating CPAP, Auto-adjust CPAP)

AutoPAP may be used as an alternative therapy for patients who are intolerant of pressures in conventional CPAP therapy and may be used for an unattended in-home CPAP titration after a positive sleep study or when follow-up indicates a need for CPAP pressure change *[A]*. It is important to follow-up with patients to determine treatment effectiveness.

	Bi-level PAP Bi-level devices have additional flow delivery methods to meet the ventilatory needs of patients with varied respiratory problems and have been shown therapeutic for OSA. Theoretical advantages of bi-level devices include reducing the work of breathing, lowering of mean treatment pressure, and a more physiologic breathing pattern. These possible advantages make a trial of bi-level devices an appropriate intervention for selected OSA patients who do not tolerate continuous pressure or auto-titrating devices. Patients with concurrent or more severe COPD or hypoventilation syndromes may also benefit, particularly if they have awake hypercapnia, but very specific criteria must be met to enable Medicare reimbursement. Although selected patients may benefit, the use of bi-level devices as initial treatment for OSA is not encouraged, since bi-level devices have not been demonstrated to be superior to CPAP in improving adherence, symptom scores, nasal discomfort, or patient complaints regarding therapy. If used, the therapeutic IPAP and EPAP pressures must be achieved by manual titration during an attended polysomnogram and many patients can resume CPAP if re-titration reveals improvement in sleep-disordered breathing with adjustment of pressure *[A]*, *[C]*. Bi-level is applied to the patient via nasal mask interface or a full-face interface. Bi-level is indicated not only to correct OSAHS, but may be used as an alternate therapy for patients who are intolerant of conventional CPAP at higher pressures. Bi-level reduces the work of breathing and lowers the mean pressure delivered in the airway.
Oral Appliances (OAs)	
AASM (2006a)	No recommendations offered.
AASM (2006b)	**Diagnosis** The presence or absence of OSA must be determined before initiating treatment with OAs to identify those patients at risk due to complications of sleep apnea and to provide a baseline to establish the effectiveness of subsequent treatment. Detailed diagnostic criteria for OSA are available and include clinical signs, symptoms, and the findings identified by polysomnography. The severity of sleep related respiratory problems must be established in order to make an appropriate treatment decision. **(Standard)** **Appliance Fitting** OAs should be fitted by qualified dental personnel who are trained and experienced in the overall care of oral health, the temporomandibular joint, dental occlusion, and associated oral

	structures. Dental management of patients with OAs should be overseen by practitioners who have undertaken serious training in sleep medicine and/or sleep related breathing disorders with focused emphasis on the proper protocol for diagnosis, treatment, and follow up. **(Option)** Although cephalometric evaluation is not always required for patients who will use an OA, appropriately trained professionals should perform these examinations when they are deemed necessary. **(Option)** **Treatment** For patients with primary snoring without features of OSA or upper-airway resistance syndrome, the treatment objective is to reduce the snoring to a subjectively acceptable level **(Standard)**. For patients with OSA, the desired outcome of treatment includes the resolution of the clinical signs and symptoms of OSA and the normalization of the AHI and oxyhemoglobin saturation. **(Standard)** OAs are appropriate for use in patients with primary snoring who do not respond to or are not appropriate candidates for treatment with behavioral measures such as weight loss or sleep-position change. **(Guideline)** Although not as efficacious as CPAP, OAs are indicated for use in patients with mild to moderate OSA who prefer OAs to CPAP, or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP or treatment with behavioral measures such as weight loss or sleep-position change. **(Guideline)** Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of OAs. Upper airway surgery (including tonsillectomy and adenoidectomy, craniofacial operations, and tracheostomy) may also supersede use of oral appliances in patients for whom these operations are predicted to be highly effective in treating sleep apnea. **(Guideline)**
AASM (2006c)	No recommendations offered.
AASM (2008)	No recommendations offered.
ICSI (2008)	**Oral Appliances**

	OAs are a recommended treatment for patients with mild OSA who have not responded to lifestyle modification or who are intolerant of PAP devices, though they are not as effective. Mandibular repositioning devices are a successful treatment modality for patients with mild OSA with obstruction in the oropharynx and tongue base region. Tongue retaining devices are helpful for patients with limited or loose natural dentition, temporomandibular disorders, and limited mouth opening. To locate a dentist or orthodontist with special training in sleep apnea who can fit oral appliances, consider contacting your local dental society, or check the following Internet Web site: www.aadsm.org.
Pharmacological Therapy	
AASM (2006a)	SSRIs are not recommended for treatment of OSA. **(Standard)** Protriptyline is not recommended as a primary treatment for OSA. **(Guideline)** Methylxanthine derivatives (aminophylline and theophylline) are not recommended for treatment of OSA. **(Standard)** Estrogen therapy (estrogen preparations with or without progesterone) is not indicated for the treatment of OSA. **(Standard)** Modafinil is recommended for the treatment of residual excessive daytime sleepiness in OSA patients who have sleepiness despite effective PAP treatment and who are lacking any other identifiable cause for their sleepiness. **(Standard)** **Supplemental Oxygen** Oxygen supplementation is not recommended as a primary treatment for OSA. **(Option)** **Medical Therapies Intended To Improve Nasal Patency** Short-acting nasal decongestants are not recommended for treatment of OSA. **(Option)** Topical nasal corticosteroids may improve the AHI in patients with OSA and concurrent rhinitis, and thus may be a useful adjunct to primary therapies for OSA. **(Guideline)**

AASM (2006b)	No recommendations offered.
AASM (2006c)	No recommendations offered.
AASM (2008)	No recommendations offered.
ICSI (2008)	**One Month Follow-Up** Patients with persistent symptoms despite adequate treatment and adherence to treatment should be evaluated for other undiagnosed sleep disorders or sleep deprivation. Modafinil has been approved by the U.S. FDA for treatment *[B]*. However, it is the consensus of this work group that a thorough evaluation of risks and benefits be done before prescribing this medication.
SURGICAL INTERVENTIONS **Abbreviations** **Back to TOC**	
AASM (2006a)	Bariatric surgery may be adjunctive in the treatment of OSA in obese patients. **(Option)**
AASM (2006b)	Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Upper airway surgery (including tonsillectomy and adenoidectomy, craniofacial operations, and tracheostomy) may also supersede use of oral appliances in patients for whom these operations are predicted to be highly effective in treating sleep apnea. **(Guideline)**
AASM (2006c)	No recommendations offered.
AASM (2008)	No recommendations offered.
ICSI (2008)	**Key Points** • Management of mild OSA may include one or more of the following treatment modalities: oral appliances, PAP devices, surgery. • Management of moderate to severe OSA includes the use of PAP devices. Patients who are intolerant of PAP devices, or those who are not adequately managed with positive airway pressure alone, may be considered for surgery.

Obesity

Incidence of OSA among morbidly obese patients is 12- to 30-fold higher than other populations, and these patients may benefit from bariatric surgery, although it must be remembered that long-term recurrence of the syndrome is possible. Surgical and non-surgical approaches to weight loss have been evaluated, although most studies to date suffer from methodological limitations including lack of random assignment to treatment groups, confounding of treatment interventions, absence of untreated controls, and lack of adequate follow-up assessment.

Surgical Procedures

The following is a list of surgical procedures available for the treatment of symptomatic anatomical obstructions of the upper airway that contribute to or result in mild clinical OSA. It may be necessary to correct the anatomical obstruction before prescribing an OA or PAP device. The work group developed this list as examples of the surgical procedures available and it is not meant to be all-inclusive of the different types of procedures available.

Septoplasty - Intranasal operation performed to straighten a deviated nasal septum (cause of substantial nasal obstruction). This procedure has a very high rate of success in improving the nasal airway if the nasal septal deviation is the major etiology of the nasal obstruction. There are, however, no controlled studies that evaluate the long-term effect of septoplasty on OSA.

Nasal polypectomy - Intranasal operation to remove nasal polyps

Tonsillectomy - Surgical procedure that involves the transoral resection of the pharyngeal tonsils. Typically this is reserved for clinically obstructing tonsillar hypertrophy of the oropharynx. There are no studies that evaluate the long-term effect of tonsillectomy on OSAHS.

Turbinoplasty - Intranasal operation performed to reduce the size of obstructing nasal turbinates. This procedure may consist of partial surgical resection of the inferior turbinates or reduction of the inferior turbinates using other methods including electrocautery, laser ablation, and radiofrequency reduction. The results of all these methods are similar. There are no studies demonstrating a beneficial effect of turbinoplasty on OSAHS.

Tracheostomy - The creation of an airway through the anterior neck into the upper trachea. This airway bypasses the entire upper airway and therefore is 100% successful in curing sleep apnea. However, this method of treatment has significant social stigmata due to the presence of a tracheostomy tube and the associated

care of the tracheostomy site. This is typically the treatment of last resort for patients with sleep apnea *[D]*.

Uvulopalatopharyngoplasty (UPPP) - The surgical resection of the obstructive portion of the velar musculature of the soft palate and the entire uvula. This surgical procedure has an approximately 52.3% rate of long-term reduction of RDI or AHI of greater than 50% of patients with mild or moderate sleep apnea.

Pillar procedures - The surgical procedure of inserting plastic rods into the palate area of the mouth to prevent the collapse of the soft palate. Small, short-term studies have shown these devices can treat mild OSA in selected patients *[D]*.

Radiofrequency ablation of the soft palate and tongue base - The administration of microwave radiofrequencies to the treated tissue of the soft palate and/or the tongue base with a needle-implanted probe. This modality has been predominantly used for the treatment of snoring by treating the soft palate. Multiple treatments are performed and complications consist of tissue erosion and perforation *[C]*.

Radiofrequency ablation of the tongue base has been described, but there are no studies demonstrating the efficacy of this method in the treatment of OSA.

Hyoid suspension - Surgical procedure that results in the hyoid bone being suspended, usually to the mandible, pulling the hyoid bone anteriorly and superiorly. The purpose of the procedure is to pull the tongue base forward, resulting in a larger hypopharyngeal airway. Complications consist of dysphagia post-treatment. There are no controlled studies evaluating this method for the treatment of OSA.

Mandibular advancement, genioglossus advancement, and/or maxillary advancement (MMA) - Orthognathic surgery, a procedure to permanently reposition the jaws, widely accepted for growth deformities and for masticatory dysfunction. The complications are low, and the results reliable. A great deal of established research in orthognathic surgery allows surgeons to use accepted techniques to help this patient population. MMA is successful for patients with base of tongue obstruction, severe OSA, morbid obesity, and failure of other treatments. Skeletal movement of the maxilla and mandible has a broad effect on the upper airway without cicatricial scarring and has demonstrated positive results. With careful evaluation, results with MMA surgery equal those of nasal CPAP. The Stanford group has outlined a specific surgical protocol that is phased and tailored to the specific anatomical abnormalities in each patient. MMA surgery is usually a two-phase surgical procedure

	[D], *[M]*, *[R]*. Refer to the original guideline document for more information on surgical procedures.
FOLLOW-UP CARE AND REFERRAL **Abbreviations** **Back to TOC**	
AASM (2006a)	No recommendations offered.
AASM (2006b)	**Follow-Up** Follow-up sleep testing is not indicated for patients with primary snoring. **(Guideline)** To ensure satisfactory therapeutic benefit from OAs, patients with OSA should undergo polysomnography or an attended cardiorespiratory (Type 3) sleep study with the OA in place after final adjustments of fit have been performed. **(Guideline)** Patients with OSA who are treated with OAs should return for follow-up office visits with the dental specialist. Once optimal fit is obtained and efficacy shown, dental specialist follow-up at every 6 months is recommended for the first year, and at least annually thereafter. The purpose of follow up is to monitor patient adherence, evaluate device deterioration or maladjustment, evaluate the health of the oral structures and integrity of the occlusion, and assess the patient for signs and symptoms of worsening OSA. Intolerance and improper use of the device are potential problems for patients using OAs, which require patient effort to use properly. OAs may aggravate temporomandibular joint disease and may cause dental misalignment and discomfort that are unique to each device. In addition, OAs can be rendered ineffective by patient alteration of the device. **(Option)** Patients with OSA who are treated with OAs should return for periodic follow-up office visits with the referring clinician. The purpose of follow up is to assess the patient for signs and symptoms of worsening OSA. Close communication with the dental specialist is most conducive to good patient care. An objective reevaluation of respiration during sleep is indicated if signs or symptoms of OSA worsen or reoccur. **(Option)**
AASM (2006c)	Close follow-up for PAP usage and problems in patients with OSA by appropriately trained health care providers is indicated to establish effective utilization patterns and remediate problems, if needed. This is especially important during the first few weeks of

	PAP use. **(Standard)** After initial CPAP setup, long-term follow-up for CPAP-treated patients with OSA by appropriately trained health care providers is indicated yearly and as needed to troubleshoot PAP mask, machine, or usage problems. **(Option)**
AASM (2008)	Patients being treated with fixed CPAP on the basis of APAP titration or being treated with APAP must have close clinical follow-up to determine treatment effectiveness and safety. This is especially important during the first few weeks of positive airway pressure (PAP) use. **(Standard)** A reevaluation and, if necessary, a standard attended CPAP titration should be performed if symptoms do not resolve or if the APAP treatment otherwise appears to lack efficacy. **(Standard)**
ICSI (2008)	**One Month Follow-Up** **Key Points**: • Follow-up visits must address effective treatment and adherence. There are no published clear guidelines defining success of therapy; therefore, the approach needs to be directed to individual patients strongly influenced by their goals, specific circumstances, and tolerance of discomfort of therapy. Evaluation to determine the success and acceptance of treatment is necessary for all patients and will indicate if further evaluation and intervention is necessary. Snoring, sleepiness, and other presenting symptoms which initiated evaluation should be reassessed at this time. If symptoms are persistent, consider a referral to a sleep specialist. The ESS (Epworth Sleepiness Scale) should be repeated at this time, as well as annually. Determination of the success of treatment should take into consideration: • Patient and bed partner satisfaction • Complications of treatment (i.e., upper airway irritation, pain from CPAP or dental device, etc.). PAP and dental device discomfort can be problematic for adherence and is influenced by many factors. Some of the most common problems and their solutions are included in Appendix B, "Management Tips to Improve Adherence with Therapy" in the original guideline document. • Adherence with therapy • Diminished sleepiness, either subjective or measured by ESS

- Diminished AHI. Since data are available linking hypertension to AHI greater than 20, it is reasonable to attempt to pursue a goal of AHI less than or equal to 20.
- Quality of life improvement

[A], *[D]*, *[R]*

Patients with persistent symptoms despite adequate treatment and adherence to treatment should be evaluated for other undiagnosed sleep disorders or sleep deprivation. Modafinil has been approved by the U.S. FDA for treatment *[B]*. However, it is the consensus of this work group that a thorough evaluation of risks and benefits be done before prescribing this medication.

PAP and dental device discomfort can be problematic, contributing to non-adherence. Patient adherence may be enhanced by direct inquiries regarding mask fit, nasal issues, PAP use less than four hours, and attending support/education classes. Follow-up questions are reflected in Appendix B, "Management Tips to Improve Compliance with Therapy" in the original guideline document. It is also important to encourage participation in an OSA educational support group, such as A.W.A.K.E. (For more information on A.W.A.K.E., log on to www.sleepapnea.org, or call 1-202-293-3650 to reach the American Sleep Apnea Association.)

Patients diagnosed with OSA are at increased risk for intra- and postoperative complications including the use of narcotics for pain management. Patients should inform their surgeon and anesthesiologist of their diagnosis of OSAHS and bring their CPAP with them for their hospital stay *[C]*.

Refer to the original guideline document for information on tools available to assess the success of therapy.

Refer to Sleep Specialist

Key Points:

- Treatment failure can be caused by many different issues, and a referral to a sleep specialist should be considered.
- Surgical options may be considered if significant anatomic problems are present.

A sleep specialist evaluation may be indicated to rule out possible causes of unsuccessful treatment, unless physical findings of obvious upper airway obstruction are present, in which case a referral to an ENT would be indicated. Specific anatomic abnormalities that may predispose to OSA include:

- Nasal obstruction

- Tonsillar hypertrophy
- Macroglossia
- Retrognathia
- Micrognathia
- Midface hypoplasia
- Elongated uvular length
- Hyoid retrusion
- Large tongue base
- Redundant pharynx
- Laryngotracheomalacia
- Benign or malignant neoplasms

The surgical procedures listed in Annotation #9, "Treatment of Mild, Moderate, or Severe OSAHS" (in the original guideline document) are available for the treatment of symptomatic anatomical obstructions of the upper airway that contribute to or result in clinical OSAHS. It may be necessary to correct the anatomical obstruction to increase the effectiveness of an OA or PAP device and a referral to ENT, a dentist or an orthodontist with special training in sleep apnea would be indicated *[M]*.

Ongoing Management

Continued follow-up should occur no less than annually in the successfully treated patient with OSA. Annual follow-up should include all the characteristics of the one-month follow-up. In addition, it is necessary to ensure annually:

- The patient's equipment has been evaluated by qualified personnel.
- Weight and blood pressure are checked.
    - If the patient is medically-complicating obese, consideration of a more aggressive weight-loss program should be pursued.
    - If there is a significant weight loss or gain, consider adjusting PAP.

Follow-up discussions may also include:

- Verification patient has current patient education materials
- Information regarding PAP and travel issues or hospital admissions
- Use of PAP with colds and sinus infections
- Long-term expectations
- Current mask/interface fit and comfort
- Mask/interface cleaning review
- Plan to replace mask/interface and supplies every six months
- Inquiry about drowsy-driving issues
- Alcohol and medication intake
- Sleep hygiene

	• Participation in the A.W.A.K.E. support group

STRENGTH OF EVIDENCE AND RECOMMENDATION GRADING SCHEMES Abbreviations Back to TOC	
AASM (2006a-c; 2008)	**Classification of Evidence** **Level I (Grade A Recommendation)**: Randomized well-designed trials with low-alpha and low-beta errors* **Level II (Grade B Recommendation)**: Randomized trials with high-alpha and beta errors* **Level III (Grade C Recommendation)**: Nonrandomized controlled or concurrent cohort studies **Level IV (Grade C Recommendation)**: Nonrandomized historical cohort studies **Level V (Grade C Recommendation)**: Case series *Alpha (type I error) refers to the probability that the null hypothesis is rejected when in fact it is true (generally acceptable at 5% or less, or p **Levels of Recommendations** **Standard**: This is a generally accepted patient-care strategy, which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or overwhelming Level II Evidence. **Guideline**: This is a patient-care strategy, which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence. **Option**: This is a patient-care strategy, which reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.
ICSI (2008)	Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as

positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent, with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M:

- Meta-analysis
- Systemic review
- Decision analysis
- Cost-effectiveness study

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

	• Medical opinion

COMPARISON OF METHODOLOGY ***Click on the links below for details of guideline development methodology***				
AASM				**ICSI**
(2006a)	**(2006b)**	**(2006c)**	**(2008)**	**(2008)**
To collect and select the evidence, searches of electronic databases were performed for all of the guidelines. AASM also performed hand-searches of published literature (primary and secondary sources) for AASM 2006b and 2008. AASM is the only group to provide names of databases searched, search terms used, and date ranges applied. Other methods used to develop the guidelines were similar. To assess the quality and strength of the evidence both groups weighted it according to a rating scheme and provide the scheme. To analyze the evidence, a systematic review with evidence tables was performed by both groups. Only AASM provides a description of the evidence analysis process. Expert consensus was employed by both groups to formulate the recommendations, and both groups provide details regarding the process. AASM is the only group to grade the strength of its recommendations according to a rating scheme. With regard to issues of cost, AASM did not perform a formal cost analysis or review published cost analyses. ICSI reviewed published cost analyses and discusses the results.				

SOURCE(S) OF FUNDING **Abbreviations** **Back to TOC**	
AASM (2006a-c; 2008)	American Academy of Sleep Medicine
ICSI (2008)	The following Minnesota health plans provide direct financial support: Blue Cross and Blue Shield of Minnesota, HealthPartners, Medica, Metropolitan Health Plan, PreferredOne and UCare Minnesota. In-kind support is provided by ICSI members.

BENEFITS AND HARMS

Abbreviations Back to TOC	
Benefits	
AASM (2006a)	Decreased incidence and severity of OSA and associated excessive daytime sleepiness, cognitive disturbances, depression, hypertension, cardiovascular disease, and cerebrovascular disease
AASM (2006b)	• Reduction of snoring to a subjectively acceptable level • Resolution of the clinical signs and symptoms of OSA • Normalization of the AHI and oxyhemoglobin saturation
AASM (2006c)	• Increased correct patient utilization of PAP devices • Improved clinical management of OSA • Identification of appropriate indications for BPAP as a second-line therapy
AASM (2008)	Appropriate use of APAP devices for titrating pressures and treating adult patients with OSA
ICSI (2008)	Appropriate diagnosis and management of patients with OSA
Harms	
AASM (2006a)	• Use of modafinil: Blood pressure must be monitored because of mild elevations reported in some OSA patients using modafinil. • Use of bariatric surgery: A cautionary note is warranted because of reports of recurrence of OSA after several years even without regaining of weight. Also, bariatric surgery is not without complications.
AASM (2006b)	Investigations show that there are many potential side effects and complications associated with OA therapy but most are minor and temporary and do not significantly affect appliance use. Many of the minor side effects (discomfort or excessive salivation) improved even with continued appliance use. However, others are more significant and do not necessarily resolve over time and may lead to discontinuation of oral appliance treatment. Some of the bite changes did not resolve with cessation of therapy and more information is needed about the significance of these occlusal changes and the risks of long-term appliance use. Conceivably, these changes may be due to frank tooth movement, remodeling of the temporomandibular joint (TMJ) complex, or neuromuscular adaptation that may have an influence on the posture of the mandible. The response of some

	patients to exercises suggests that it may be related to a failure to reposition the mandible into the glenoid fossa. Additional cephalometric, radiographic, and clinical studies are needed to elucidate the importance of these changes. For further details on adverse events, see the companion review document listed in the "Availability of Companion Documents" field of the NGC summary.
AASM (2006c)	While sinusitis, mask leaks, and dermatitis are not infrequent, tinnitus and dyspnea occur more rarely. A listing of adverse events associated with PAP therapy is presented in Table 3 of the accompanying review paper (see "Availability of Companion Documents" field in the NGC summary of this guideline).
AASM (2008)	Not stated
ICSI (2008)	PAP and dental device discomfort can be problematic, contributing to non-adherence. (Refer to Appendix B in the original guideline document for more information.) **Potential Adverse Effects of Surgical Procedures** • Tracheostomy has been associated with significant social stigma due to the presence of a tracheostomy tube and the associated care of the tracheostomy site. • Radiofrequency ablation of the soft palate and tongue base requires multiple treatments and is associated with tissue erosion and perforation. • Hyoid suspension complications include dysphagia post-treatment.

CONTRAINDICATIONS Abbreviations Back to TOC	
AASM (2006a)	Not stated
AASM (2006b)	**Dental Contraindications** Patients need to have an adequate number of healthy teeth (not compromised by periodontal disease) in the upper and lower dental arch to use a mandible repositioning appliance (MRA). The exact

	number of teeth necessary for adequate support of an MRA has not been identified but consensus holds that at least 6 to 10 teeth in each arch is desirable. Consensus opinion is that the patient should have the ability to protrude the mandible forward and open the jaw widely without significant limitation in order to be fitted with an MRA. Moderate to severe temporomandibular joint (TMJ) problems or an inadequate protrusive ability may be contraindications to OA therapy. Not all TMJ problems are a contraindication to OA therapy — mild TMJ problems may be lessened by the forward jaw position. Significant bruxism may be a contraindication to OA therapy. Some patients may damage the appliance if they have severe bruxism or may have increased pain if the appliance rigidly holds them in a single fixed position. Patients with full dentures are generally unable to use an MRA but some of these patients may be treated with a tongue device (TD).
AASM (2006c)	Not stated
AASM (2008)	Not stated
ICSI (2008)	Not stated

Abbreviations
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AASM, American Academy of Sleep Medicine

A.W.A.K.E., Alert Well and Keeping Energetic

AHI, apnea-hypopnea index

APAP, auto-titrating continuous positive airway pressure

BPAP, bi-level positive airway pressure

CHF, congestive heart failure

COPD, chronic obstructive pulmonary disease

CPAP, continuous positive airway pressure

DME, durable medical equipment

ENT, ear, nose, and throat

EPAP, expiratory positive airway pressure

ICSI, Institute for Clinical Systems Improvement

IPAP, inspiratory positive airway pressure

MMA, maxillary mandibular advancement

OA, oral appliance

OSA, obstructive sleep apnea

OSAHS, obstructive sleep apnea/hypopnea syndrome

PAP, positive airway pressure

RDI, respiratory disturbance index

SSRI, selective serotonin reuptake inhibitors

TMJ, temporomandibular joint

UPPP, uvulopalatopharyngoplasty

This synthesis was prepared by ECRI on May 17, 2007. The information was verified by ICSI on August 8, 2007, by SIGN on August 24, 2007, and by AASM on October 31, 2007. This synthesis was revised February 4, 2009 to update ICSI recommendations and again in March 2010 to remove SIGN recommendations and add AASM 2008 recommendations. The information was verified by AASM on April 14, 2010.

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